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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,104	02/14/2006	Ivan Kamiel De Scheerder	DCB-06-1060	2612

35811 7590 03/02/2010

IP GROUP OF DLA PIPER LLP (US)
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EXAMINER	
GANESAN, SUBA	
ART UNIT	PAPER NUMBER
3774	

NOTIFICATION DATE	DELIVERY MODE
03/02/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pto.phil@dlapiper.com

Office Action Summary	Application No.	Applicant(s)	
	10/595,104	DE SCHEERDER ET AL.	
	Examiner	Art Unit	
	SUBA GANESAN	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,14 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 14-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's claim amendments are sufficient to overcome the previously applied rejections under 35 USC 112.

2. Applicant's arguments filed 10/15/2009 have been fully considered but they are not persuasive. Applicant argues that because Kaplan does not provide an example of how to inhibit restenosis or data concerning efficacy of the disclosed antioxidants that Kaplan is not purely speculative. On this basis, Applicant concludes that Kaplan is not sufficiently disclosed to be enabling. Examiner disagrees.

3. The prior art is presumed to be operable and enabling, and efficacy is not a requirement for prior art enablement (See MPEP 2121). The prior art's lack of example or specific data of efficacy are insufficient reasons to rebut the presumption of enablement.

4. Applicant argues that Kaplan's disclosure of mass per kg body weight units do not enable dosage units for a prosthesis. This is not persuasive. Kaplan specifically discloses use of implantable stents (pg. 9 lines 2-10). Examiner considers the treatment of restenosis the same as a healing response after implantation of a prosthesis.

5. Applicants arguments regarding melatonin as an oxygen-free radical scavenger are not persuasive. First, this limitation is not required by the claims. Second, even if it were required, the prior art still anticipates the product, because inherent features of the prior art need not be recognized at the time of the invention (See MPEP 2112). Finally,

this limitation would not alter the structure of the claimed invention and thus would be treated as a functional limitation.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 7, 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaplan (WO 98/30255) as cited in applicants' IDS.

3. Kaplan discloses a stent comprising a releasable therapeutic agent comprising melatonin (col. 6 lines 5-18), the therapeutic agent being present in an effective amount to modify the healing response of the vessel wall after tissue injury (Kaplan discloses the use of melatonin to treat restenosis).

4. The melatonin is coated on the stent. The stent can be a wire stent (see pg. 9 lines 2-10, noting that U.S. Pat. No.: 5342348 is a wire stent). The stent can form uniform thickness struts (see U.S. Pat. No.: 5342348).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan (WO 98/30255) in view of Shanley (Pub. No.: US 2002/0082680)

7. Kaplan is explained supra. However, Kaplan lacks recesses in the stent struts. Shanley teaches the use of recesses in stent struts for the purpose of delivering therapeutic agent to site of implantation (see abstract). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the stent of Kaplan with recesses as taught by Shanley for the purpose of delivering therapeutic agent. Such a modification of Kaplan would be a simple substitution of known drug delivery means, and would have occurred using known methods, yielding predictable results.

8. Claims 8-9, 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan (WO 98/30255).

9. Kaplan is explained supra. However, Kaplan either lacks or does not specify the total load of melatonin or the time period for release of the melatonin. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a total load of melatonin of at least .001μg/mm2 and a release for at least 6 hours, since both specified ranges would simply be an optimization of the disclosed drug combined with the disclosed stent of Kaplan. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

10. Kaplan lacks teaching for a shunt, however, a stent may be used as a shunt. Additionally, shunts are well known medical devices. If not inherent in Kaplan, it would have been obvious to one of ordinary skill in the art to apply the melatonin drug to a shunt device instead of a stent device for the purpose of treating restenosis along the shunted region.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. G./
Examiner, Art Unit 3774

/DAVID ISABELLA/
Supervisory Patent Examiner, Art Unit 3774